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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/042,644	01/08/2002	Jacques F. Banhereau	13786-7	7691

45473 7590 06/24/2009
BRINKS, HOFER, GILSON & LIONE
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MORRISVILLE, NC 27560

EXAMINER

CHANDRA, GYAN

ART UNIT	PAPER NUMBER
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1646

MAIL DATE	DELIVERY MODE
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06/24/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.		Applicant(s)	
	10/042,644		BANCHEREAU ET AL.	
	Examiner		Art Unit	
	GYAN CHANDRA		1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 May 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 99 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 99 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>5/6/2009</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's response filed on 5/6/2009 is acknowledged and fully considered.

Status of Application, Amendments, And/Or Claims

The amendments of claim 1 and the cancellation of claims 1-98 and 100-103 have been made of record.

Claim 99 is pending and under examination.

Information Disclosure Statement

The IDS submitted on 5/6/2009 has been considered.

Response to Arguments

Claim Rejections - maintained

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 99 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Skurkovich (5,888,511) for the reasons of record on pages 3-6 of the office action mailed on 11/07/2008.

The instant claims are broadly drawn to a method of treating an autoimmune disease in a subject comprising administering a composition consisting of one or more antibodies consisting of one or more humanized or human monoclonal anti-IFN- α antibodies or antigen-binding fragments thereof and a diluent, a preservative, a solubilizer, an emulsifier, an adjuvant, a carrier, a buffer, a pharmaceutical additive, a detergent, an anti-oxidant, a bulking substance, a tonicity modifier, a flavoring agent, a lubricant, a suspending agent, a filler, a glidant, a compression aid, a binder, a tablet-disintegrating agent, an encapsulating material, a sweetener, a thickening agent, a color, a viscosity regulator, a stabilizer, an osmo-regulator, a pharmaceutically acceptable propellant, a flavorant, a dye, a coating, or a combination of any thereof, wherein said autoimmune disease is psoriasis.

Applicants argue (see page 4 of Response) that the reference Skrkovich does not teach an effective treatment for psoriasis comprising administering a composition consisting of humanized monoclonal antibodies against interferon- α alone. Applicants argue that there is no motivation to modify Skurkovich et al nor is any reasoning provided as to why a skilled artisan would modify the reference to arrive at methods for the treatment of psoriasis is being currently claimed.

Applicants' arguments have been fully considered but they are not persuasive because the reference Skurkovich et al teach that autoimmune disease results when an individual's immune system attacks his own organs or tissues, producing a clinical condition associated with the destruction of that tissue, as exemplified by diseases such as rheumatoid arthritis, insulin-dependent diabetes mellitus, acquired immunodeficiency syndrome ("AIDS"), hemolytic anemias, rheumatic fever, Crohn's disease, Guillain-Barre syndrome, psoriasis, thyroiditis, Graves' disease, myasthenia gravis, glomerulonephritis, autoimmune hepatitis, multiple sclerosis, systemic lupus erythematosus (col. 1, lines 35+). Skurkovich et al treating rheumatoid arthritis (see Example 3, Table 2) and AIDS (see Example 7) by administering an anti-IFN- α antibody. They incorporate the reference Skurkovich et al Med. Hypoth. 42: 27-35 (1994) and the reference is also considered in the IDS filed on 9/25/2006)) which teaches that interferon alpha is present in patients having psoriasis, on specific cells within affected skin lesions (right column, 5th line from the bottom). They teach treating RA patients with anti-interferon antibodies (page 30, Treatment with anti-interferon antibody). Page 33 of the reference clearly recites "Some diseases and conditions

connected with IFN disturbance or hyperproduction in which IFN removal may be beneficial” and the list includes psoriasis. Therefore, one of the skill in the art would be motivated in treating a patient having psoriasis with an antibody against IFN- α . The prior art teaches the term "antibody" is intended to include monoclonal or polyclonal antibodies, or a combination thereof, humanized forms of the monoclonal antibodies (comprising only human antibody protein), and chimeric monoclonal antibodies, as well as biologically active fragments, functional equivalents, derivatives, or allelic or species variants thereof (col. 15, lines 2+). Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time of invention was made to treat psoriasis which is an autoimmune disease where interferon alpha antibody is present in the blood of a subject by administering a monoclonal antibody against interferon- α as taught by Skurkovich et al. The motivation comes from the reference Skurkovich et al Med. Hypoth. 42: 27-35 (1994) which is incorporated in prior art and which clearly states that patients with psoriasis having disturbance in IFN alpha would benefit from the removal of IFN- α . Therefore, the rejection is maintained.

Conclusion

Claim 99 is rejected.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GYAN CHANDRA whose telephone number is (571)272-2922. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol can be reached on (571) 272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

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USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Gyan Chandra/
Examiner, Art Unit 1646

/Robert Landsman/
Primary Examiner, Art Unit 1647